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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,779	04/20/2001	Amin I. Kassis	U0381-00001	2010
21874	7590	11/20/2006	EXAMINER	
EDWARDS & ANGELL, LLP			HANLEY, SUSAN MARIE	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,779

Applicant(s)

KASSIS ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-92 is/are pending in the application.
- 4a) Of the above claim(s) 56-58, 64-67 and 69-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 54, 55 and 76-92 is/are allowed.
- 6) ☒ Claim(s) 50-53, 59-63 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/06 has been entered.

Status of the Claims

Claims 50-92 are pending. The rejections against claim 54 and the claims depending therefrom have been overcome by Applicant's arguments, see pages 8-12, filed 7/14/06. Thus, claims that depend from claim 54, but which had been withdrawn, are now rejoined. Applicant's arguments filed 7/14/06 have overcome the rejection of claim 50, and claims depending therefrom, under 35 USC 103. However, a new rejection over the same claims (including the same previously elected species) is being made in this Office action. Thus, in view of the previously required election, claims 56-58, 64-67, and 69-75, stand withdrawn from further examination. Applicant is directed to the Response filed July 16, 2002 wherein the R1 specie "gamma emitter" was elected. "Boron cage," as in instant claim 67, was not elected and therefore stands withdrawn.

Claims 50-55, 59-63, 68 and 76-92 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

As noted supra, Applicant's arguments, see pages 8-12, filed 7/14/06, with respect to the rejection(s) of claim(s) 50-53, 59-63 and 68 under 35 U.S.C. 103(a) as being unpatentable over Pastan (US 5,489,525) in view of Haugland (US 5,316,906) and Hansen (US 5,851,527), Lebioda et al. (US 5,763,490),

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Mertens (US 5,021,220) and Christenson (US 4,107,285) and the rejection of claims 54, 76-80 and 85 under 35 U.S.C. 103(a) as being unpatentable over Pastan (US 5,489,525) in view of Haugland (1995), Haugland (US 5,316,906) and Hansen (US 5,851,527), Lebioda et al. (US 5,763,490), Mertens (US 5,021,220) and Rose (US 5,816,259) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the following.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

This application is claiming the benefit of prior-filed provisional application under an unknown serial number under 35 U.S.C. 119(e). As noted, neither the declaration nor the application information clearly identify the serial number for this provisional application. Hence, the priority date for this application is the filing date of April 20, 2001.

Specification

The specification is objected to because it contains a reference for priority to an unknown provisional application.

Claim Rejections - 35 USC § 112

Claim 77 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 77 is rejected because the meaning of "a 'incase" in the penultimate line of the claims is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 50-53, 59-63 and 68 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ho et al. (ACS Meeting on April 1-5, 2001) in light of Pero et al. (US 6,538,038; previously cited by the Examiner).

Ho discloses an in vivo method for the extracellular localization of an insoluble radioactive moiety that is part of a water soluble prodrug, wherein an I-125 labelled quinazolinone compound having a 2-phosphoryl group is administered to mice and phosphatase endogenous to the tumor cells cleaves the prodrug to yield the radioactive precipitate trapped within the tumor mass.

Pero et al. disclose a method of achieving targeted vascular destruction at a locality of proliferating vasculature. The method comprises administering to a warm-blooded animal a prodrug that is substantially non-cytotoxic and water soluble wherein said prodrug is converted by endogenous, extracellular phosphatase located at the site of proliferating vasculature to a water-insoluble, cytotoxic drug. Pero et al. teach that their method is effective because injured microvessels exhibit a high level of phosphatase activity compared to non-injured vessels and said phosphatases are extracellular.

Given that phosphatase is known to be an extracellular enzyme, the entrapment of the I-125 labelled quinazolinone compounds inherently occurs in the extracellular proliferating vasculature of the tumor.

This rejection is made under 35 USC 102(a) because the prior art is by another. The filing date of the instant application is April 20, 2001. Kassis and Harapanhalli are listed as the inventors. However, the cited reference includes Ravi, Bassan and Adelstein who are not named as inventors.

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The disclosure by Pero et al. is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the definition of a kit. MPEP 2131.01.

The following prior art is cited to further demonstrate the state of the prior art with respect to localization of compounds at tumor sites:

Cox et al. "A high-resolution, fluorescence-based method for localization of endogenous alkaline phosphatase activity" J. Histochem. Cytochem. (1999) 47(11): 1443-1455.

McCarty, M. "Non-toxic inhibition of extracellular tumor enzyme" Medical Hypotheses (1982) 8(3): 303-310.

Unak et al. " Synthesis and Iodine-125 labeling of glucuronide compounds for combined chemo- and radiotherapy of cancer" Appl. Radiation Isotopes (1997) 48(6): 777-783.

Unak, T. "Potential use of radiolabeled glucuronide prodrugs with auger and/or alpha emitters in combined chemo- and radio-therapy of cancer" Current Pharmaceutical Design (2000) 6: 1127-1142.

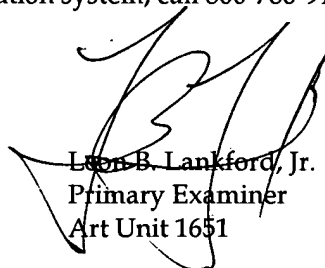
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



Leon B. Lankford, Jr.
Primary Examiner
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